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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,582	08/15/2001	Jonathan Stanley Harold Denyer	102199-201	3302
30031	7590	05/18/2005		
MICHAEL W. HAAS, INTELLECTUAL PROPERTY COUNSEL RESPIRONICS, INC. 1010 MURRY RIDGE LANE MURRYSVILLE, PA 15668				
			EXAMINER MENDOZA, MICHAEL G	
			ART UNIT 3731	PAPER NUMBER

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/930,582

Applicant(s)

DENYER ET AL.

Examiner

Michael G. Mendoza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3 and 5-18 is/are pending in the application.
- 4a) Of the above claim(s) 13-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-8 and 12 is/are rejected.
- 7) ☒ Claim(s) 9-11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/781,610.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments filed 22 February 2005 have been fully considered but they are not persuasive. The Applicant has amended the claim to include the limitation of "a data carrier onto which the drug delivery device is arranged to place the information for a number of drug deliveries". The Denyer reference still reads on the claim i.e., "the total dose of medicament received by the patient is calculated by summing the dose of medicament received in each inhalation breath". Each breath will contain a dose of medicament. Each dose of medicament is a drug delivery. The statement of "summing" means there is more than one breath taken.

### ***Double Patenting***

2. Claim 12 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 7. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Election/Restrictions***

3. Newly submitted claims 13-18 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original claims are directed to an apparatus. Newly submitted claims 13-18 are directed to a method.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 13-18 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 3, 5, and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Denyer et al. 6192876

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

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6. Denyer et al. teaches a system for delivery of a drug to a patient comprising: a drug delivery device arranged to delivery a dose of the drug to the patient over a plurality of breaths, the device including a breath analyzer which (i) analyses a patient's breathing during the drug delivery, wherein the analysis by the breath analyzer includes quantitatively measuring at least one parameter of the patient's breathing; and (ii) generates breath information on a patient's breathing during drug delivery wherein the breath information includes the at least one quantitative measurement of the patient's breathing (col. 3, lines 21-33); a data carrier; a data analyzer and a trend generator (col. 3, lines 57-63); and means for identifying non-compliant use of the drug delivery device (col. 3, lines 54-56).

7. Claims 1, 6-8, and 12, are rejected under 35 U.S.C. 102(e) as being anticipated by Denyer et al. 6584971.

The applied reference has a common Assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

8. Denyer et al. teaches a system for delivery of a drug to a patient comprising: a drug delivery device arranged to delivery a dose of the drug to the patient over a plurality of breaths, the device including a breath analyzer which (i) analyses a patient's breathing during the drug delivery, wherein the analysis by the breath analyzer includes

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quantitatively measuring at least one parameter of the patient's breathing; and (ii) generates breath information on a patient's breathing during drug delivery wherein the breath information includes the at least one quantitative measurement of the patient's breathing (col. 3, lines 28-39); a data carrier (col. 3, lines 34-35); a data analyzer (col. 3, lines 36-37) and a trend generator (col. 7, lines 17-21); and wherein the breath information includes inhalation time and a total number of pulses, and wherein the breath information includes inhalation time and a total number of pulse, and wherein the data analyzer calculates a mean inhalation time value by dividing the total inhalation time by the total number of pulses (col. 1, line 63 – col. 2, line 16); wherein the breath information includes inhalation time and exhalation time and wherein the data analyzer calculates an inhalation to exhalation ratio value by dividing the total inhalation time by the total exhalation time (col. 11, lines 17-28).

#### ***Allowable Subject Matter***

9. Claims 9-10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### ***Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MM



GLENN K. DAWSON  
PRIMARY EXAMINER